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10/776,576	02/11/2004	Krzysztof Sowinski	760-102 DIV	2790
23869 7590 10/15/2008 HOFFMANN & BARON, LLP 6900 JERICHO TURNPIKE			EXAMINER	
			BUTLER, PATRICK NEAL	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 10/776,576 SOWINSKI ET AL. Office Action Summary Examiner Art Unit Patrick Butler 1791 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 27 June 2008. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-20 is/are pending in the application. 4a) Of the above claim(s) _____ is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 1-20 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date. ___ Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) Notice of Informal Patent Application

6) Other:

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DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4 and 6-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The comparison to "expanded polytetrafluoroethylene tube" in Claim 4, line 3, is not found in the Specification as originally filed. Although the Specification discloses the stretch capabilities of the stent and tubular structure (see [0038]), the comparison between the finished ePTFE tubular structure in stretched and unstretched states. Ratios are claimed between the finished ePTFE tubular structure and an intermediate structure. Claims 6-12 are rejected via their dependency.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 and 6-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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With respect to Claim 4, the "increased longitudinal elongation and radial expansion and recovery properties" are not clear which intermediate property is being compared to, since the intermediate tube is an "expanded polytetrafluoroethylene tube" twice: once longitudinally and once radially. For purposes of examination, the Examiner assumes that the properties are increased in the final tubular structure from the properties of original tubular structure. Claims 6-12 are rejected via their dependency.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Omum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 14, and 18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 2 of copending Application No. 11/026,657. Although the conflicting claims are not identical, they are not patentably distinct from each other because, with respect to instant Claims 1 and

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18, Claim 12 of copending Application No. 11/026,657 claims providing an ePTFE tube, longitudinally expanding the tube, and transversely expanding the tube. With respect to instant Claim 14, Claim 2 of copending Application No. 11/026,657 claims providing an ePTFE tube, expanding the tube, and sintering the tube (heat treating the tube).

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by House (US Patent No. 4,877,661).

With respect to Claim 1, House teaches making a PTFE tube (see col. 2, lines 55-60) by length stretching a PTFE tube that has longitudinal axes of the fibrils that are all substantially parallel (longitudinally stretching said polytetrafluoroethylene tube to form an expanded polytetrafluoroethylene tube, wherein said expanded polytetrafluoroethylene tube is comprised of fibrils oriented in a longitudinal direction of said tube and nodes oriented in a circumferential direction of said tube) (see fig. 1 and col. 2, line 61 through col. 3, line 12). House teaches biaxially stretching the tube (col. 2, line 61 through col. 3, line 12), which necessarily includes radial expansion (placing the expanded polytetrafluoroethylene tube circumferentially exterior to a longitudinal

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foreshortening and radially expanding mechanism; applying radial pressure from the longitudinal foreshortening and radially expanding mechanism; radially expanding and longitudinal foreshortening said expanded polytetrafluoroethylene tube over said longitudinal foreshortening and radially expanding mechanism), and compressing, in a direction parallel to but opposite to the direction in which it was originally expanded by stretching, over a mandrel, which would necessarily cause longitudinal foreshortening and radial expansion (placing the expanded polytetrafluoroethylene tube circumferentially exterior to a longitudinal foreshortening and radially expanding mechanism; applying radial pressure from the longitudinal foreshortening and radially expanding mechanism; radially expanding and longitudinal foreshortening said expanded polytetrafluoroethylene tube over said longitudinal foreshortening and radially expanding mechanism) (see col. 3, lines 24-29 and col. 6, lines 47-53), which makes the fibrils wavy (to reorient said fibrils non-longitudinally to form an ePTFE tubular structure with reoriented fibrils) (see fig. 2 and col. 4, lines 21-24). The compressing would necessarily cause radial expansion given the interior mandrel (see col. 6, lines 47-53) and lack of wrinkling or crimping (see col. 3, lines 24-29).

With respect to Claim 2, the compression was done at 100-380 °C (200-720 °F) (see col. 6, lines 57-63 and Table 1, col. Oven Temp. °C for samples 1-5).

With respect to Claim 3, the fibrils are made wavy, which would require rotation at the nodes to maintain continuity from node to wave to node (reoriented fibrils are hingeably rotated about said nodes) (see fig. 2 and col. 4, lines 21-24).

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With respect to Claim 4 and 6-11, House's method of making a PTFE tube would result in a final tubular structure whose longitudinal elongation and radial expansion and recovery properties are increased from the properties of original tubular structure (Claim 4 and 12) and whose longitudinal (Claims 6-8) and radial (Claims 9-11) expansion properties are as claimed principally because House's method uses the same steps as claimed to achieve the final structure.

With respect to Claim 5, the stretching does not result is length change of the fibrils since their only appearance change is being bent or wavy in microscopic representation (see col. 4, lines 16-31 and figs. 1 and 2).

With respect to Claim 13, the nodes' lengths would necessarily expand during the radial pressure principally because they are within the same tube as claimed and subjected to the same steps as claimed.

With respect to Claim 14, House teaches that the stretched tube is heated while restrained to a temperature above its crystalline melt point and held there for a period of time (suspending and heating said PTFE tube after longitudinal expansion and prior to placing said tube on said expanding mechanism) (see col. 3, lines 3-12).

With respect to Claim 15, House's heating step would affect the tube's structural integrity as claimed principally because House's method uses the same steps as claimed to achieve the final structure.

With respect to Claim 16, House teaches making a PTFE tube as applied to Claim 1 above. Moreover, House teaches compression was done at 100-380 °C (200-720 °F) (see col. 6, lines 57-63 and Table 1, col. Oven Temp. °C for samples 1-5).

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House's method teaches reorienting the fibrils hingeably about said nodes (see figs. 1 and 3).

With respect to Claim 17, House teaches compression was done at 100-380 °C (200-720 °F) (see col. 6, lines 57-63 and Table 1, col. Oven Temp. °C for samples 1-5).

With respect to Claim 18, House teaches making an ePTFE tube as applied to Claim 1 above. House's method teaches reorienting the fibrils hingeably about said nodes (see figs. 1 and 3). House's method of making an ePTFE tube would result in a final tubular structure whose nodal orientation has a greater length between said nodes after radial expansion than before principally because House's method uses the same steps as claimed to achieve the final structure.

With respect to Claim 19, House teaches compression was done at 100-380 °C (200-720 °F) (see col. 6, lines 57-63 and Table 1, col. Oven Temp. °C for samples 1-5).

With respect to Claim 20, House's method of making an ePTFE tube would result in a final tubular structure whose reoriented fibrils are longitudinally straighter than said fibrils of expanded polytetrafluoroethylene tube principally because House's method uses the same steps as claimed to achieve the final structure.

Response to Arguments

Applicant's arguments filed 11 March 2008 and 27 June 2008 have been fully considered but they are not persuasive.

Applicant argues with respect to the 35 USC 112, second paragraph, rejections. Applicant's arguments appear to be on the grounds that:

1) The 35 USC 112 rejections are obviated by amendments made.

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Applicant argues with respect to the double patenting rejections. Applicant's arguments appear to be on the grounds that:

- The rejection over US Patent No. 6,716,239 is moot in view of the restriction requirement during its prosecution.
- Rejection of Claims 1 and 14 over copending application number 11/206,657's
 Claim 2 are moot in view of Claim 1's amendments.

Applicant argues with respect to the 35 USC 102 rejections. Applicant's arguments appear to be on the grounds that:

- House's steps do not constitute radial expansion since the second action is parallel to longitudinal stretching and thus not perpendicular to longitudinal stretching.
 - 5) Moreover, House does not rotate fibrils about hinges.

The Applicant's arguments are addressed as follows:

- 1) In view of Applicant's amendment of Claims 1 and 4 to include proper antecedent basis, the Examiner withdraws the previously set forth 35 U.S.C. 112, second paragraph rejection as detailed in the Claim Rejections - 35 U.S.C. 112 section of the Office Action dated 13 December 2007. However, as necessitated by Applicant's Amendments, new 35 U.S.C. 112, first and second paragraph, rejections are made as recited above.
- 2) Applicant's arguments with respect to the double patenting rejection over US Patent No. 6,716,239 have been fully considered and are persuasive. The double patenting rejection over US Patent No. 6,716,239 has been withdrawn.

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3) Applicant's arguments with respect to instant Claim 1's double patenting rejection over copending application number 11/206,657's Claim 2 is moot in view of instant Claim 1's double patenting rejection over copending application number 11/206,657's Claim 12.

- Moreover, newly claim limitation are taught by the claims of copending application number 11/206,657 as recited in the double patenting rejection above.
- House teaches biaxially stretching the tube (col. 2, line 61 through col. 3, line
 which necessarily includes radial expansion.
- 4) Moreover, the compressing would necessarily cause radial expansion given the interior mandrel (see col. 6, lines 47-53) and lack of wrinkling or crimping (see col. 3, lines 24-29).
- 4) Moreover, the radial expansion portion does not exclude radial expansion due to compression. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., radial expansion not resulting from compression) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).
- House's method teaches reorienting the fibrils hingeably about said nodes (see figs. 1 and 3).

Conclusion

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Butter whose telephone number is (571) 272-8517. The examiner can normally be reached on Mon.-Thu. 7:30 a.m.-5 p.m. and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson can be reached on (571) 272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/P. B./ Examiner, Art Unit 1791

/Monica A Huson/ Primary Examiner, Art Unit 1791